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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/648,692      | 08/25/2000  | J. Oliver Dolly      | 17311(AP)           | 6378             |

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT PAPER NUMBER

1656

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/648,692

Applicant(s)

DOLLY ET AL.

Examiner

Gabriele E. BUGAISKY

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-28, 32, 33 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-28, 32-33, 38-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

The amendment of 22 June 2005 is acknowledged. Claims currently pending are 20-28, 32-33, and 38-47

#### ***Oath/Declaration***

The oath or declaration remains defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required.

See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicants' comment that a new oath will be submitted is noted.

#### ***Specification***

The abstract of the disclosure remains objected to because the first sentence contains no verb. Correction is required. See MPEP § 608.01(b).

The amendment is noted; however, the first sentence still lacks a verb. The phrase that begins with "that comprises" is not a verb for the noun "compositions", but is a dependent phrase. It is suggested that the sentence end with e.g., "are provided".

#### ***Claim Objections***

Claims 39 and 47 are objected to because of the following informalities: "comprising" is not a verb. It is suggested that it be amended to "comprises". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-28, and 38-47 are rejected and claims 32-33 remain rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20, and 40 each recite in d)” . . . a peptide comprising a non-native clostridial neurotoxin protease cleavage site”. It is unclear what is meant by this. Is it a protease cleavage site which is not recognized by a clostridial protease, is it a cleavage site not normally present in clostridial neurotoxins, etc. is it a cleavage site not recognized by a specific host cell, etc. Claims 21-28, 32-33, 38-39 and 41-47 are included in this rejection as they depend from the above claims and do not clarify the ambiguity.

Claim 32 recites the limitation “ a) inserting the plasmid of any of claims 20-28, 31 or 38. . . ”

There is insufficient antecedent basis for this limitation (plasmid) in claims 20-28 and 38, as the amended claims now recite only “nucleic acid molecule”. Further, the claim depends, in the alternative, from cancelled claim 31. Since there is no claim 31, it is not clear what Applicants intend by the “plasmid of claim 31”.

Claim 33 recites the limitation “a) ...the plasmid of either of claims 21 or 22. . . ”

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There is insufficient antecedent basis for this limitation (plasmid) in claims 21 or 22, as the amended claims now recite only "nucleic acid molecule".

***Claim Rejections - 35 USC § 102***

The rejection of claims 20, 23-29,32 and 35-37 under 35 U.S.C. 102(b) as being anticipated by WO98 /07864 (Shone *et al.*), is withdrawn. The reference does not teach a nucleic acid encoding a clostridial derived protein with an altered protease cleavage site between the H and C chains.

The rejection of claims 20, 23-29,32 and 35-37 under 35 U.S.C. 102(e) as being anticipated by Shone *et al.*(US patent 6461617.), is withdrawn. The reference does not teach a nucleic acid encoding a clostridial derived protein with an altered protease cleavage site between the H and C chains.

***Claim Rejections - 35 USC § 103***

The rejection of claims 20-29, 32-33 and 35-37 under 35 U.S.C. 103(a) as being unpatentable over Shone *et al.* (US patent 6461614), is withdrawn. The reference does not teach a nucleic acid encoding a clostridial derived protein with an altered protease cleavage site between the H and C chains.

***Conclusion-***

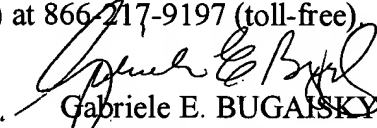
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gabriele E. BUGAISKY  
Primary Examiner  
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